REMARKS

Claims 8 to 13 are pending in the application.

Claim Rejections - 35 U.S.C. 112

Claims 9 and 12 stand rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite.

In claim 9, the term "unitary" has been added to "cylinder wall" so as to eliminate ambiguity.

In claim 12, "earth's" has been deleted as the term horizontal stands on its own.

Reconsideration and withdrawal of the rejection of the claims under 35 USC 112 are respectfully requested.

Rejection under 35 U.S.C. 102

Claims 8 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Whaley et al. (US 6,119,688).*

The basic principle of the device according to the invention for taking powdered, grainy, or granular substances resides in that only in the inhalation-ready state of the device a continuous air channel with Venturi tube-like or smooth profile is made available for guiding the airflow while in the state of non-use the air channel is completely blocked so that in the intake area no air can be sucked in and in the outlet area (supply tube) no powder-carrying air can be sucked in. In this way, exclusively at the time of administering medication an appropriately shaped air channel enables an optimal flow course and, while providing a perforce synchronization between deposition of the powder and inhalation, the portioned powdered medicament is entrained and dispersed sufficiently along the subsequent diffusor stretch of the supply tube. Even in the case of acute breathing problems, the patient can still provide the breathing power required for the powder aerosol treatment with the inhaler because straight airflow channels can be realized. In the state of non-use, on the other hand, the intake opening and the outlet opening are automatically sealed with regard to moisture and dust.

The synchronously operating dosing and releasing device enables the minimization of components and closes off the entire inner system of the device in an airtight and water-tight way when not in use. The patient opens the airflow channel in the device with a single movement of the supply tube. When doing so, the powder is deposited and can be inhaled

immediately. After inhalation, the patient closes the system again with a single movement by pivoting the supply tube. When doing so, the next dose is portioned from the storage receptacle and the system is airtightly closed. The pivot system provides a perforce correct manipulation of the device for safe administration. A one-way valve on the intake side can provide absolute seal-tightness.

Since aside from the supply tube no additional devices must be moved for readying the powder inhaler for operation, during the inhalation process the major portion of the inhalation energy remains available in fact for inhalation because of the straight configuration of the airflow channel. Because only a few mechanical parts are provided on the inhaler and the airflow is guided almost linearly, only minimal proportions of the powder remain within the device, i.e., adhere to the air channel. This increases the dosing precision. By being entrained by the airflow, the powder is uniformly distributed and de-agglomerated.

The air channel preferably has the shape of a Venturi tube or Laval nozzle. In addition, during transport of the powder and entrainment by the airflow optionally larger powder particles are broken up and thus comminuted by means of helical lamellas. Mechanical resistance devices / de-agglomeration devices of any shape can be positioned within the air channel in order to vary the air channel as needed. The air channel, depending on the requirements of the powder, can be freely varied with regard to breathing resistance. The configurations of the air channel can be round or oval in cross-section and can have the same cross-sectional shape across the entire length. The intake and outlet can be, for example, funnel-shaped. By means of the Venturi tube, an optimal flow and acceleration of the inhaled airflow including entrainment and dispersion of the powdered medicament is ensured. In particular, a perforce complete emptying is ensured. The free design of the air channel enables the adaptation of the inhaler to different inhalable medicaments. For example, dry powdered medicaments can be dispersed within the airflow in particle-defined size.

The inhaler according to the invention as a whole is suitable for extended use because, due to the configuration, the entire air channel can be easily cleaned by means of a pipe cleaner and hygienic problems can be avoided. The inhaler is comprised of a few injection-molded parts without using springs and levers while it provides full functionality

and simplest shape. The same advantages as described above in connection with a powder inhaler result also for grainy or granular substances which, however, are not inhaled but instead flow in a dosed portion from the device according to the invention and can be used accordingly. The difference to the powder inhaler is that no continuous airflow for inhalation is generated by the user.

Whaley et al. discloses a device 10 for taking powdered medicaments 12 through mouthpiece 15. A medicament reservoir 11 is provided in which the medicament 12 to be inhaled is stored. The device comprises furthermore a stationary hollow cylinder 22 that functions as a pressure reservoir. This pressure reservoir has an opening 23. This opening 23 is aligned with the mouthpiece 15 at all times. The cylinder (dosage member) 30 is rotatably supported on the stationary cylinder 22. This dosage member 30 has a dosage chamber 32. In the position of non-use (Fig. 3) medication 12 falls from the reservoir 11 into the opening 32 of the rotatable cylinder 30. The cylinder 30 is rotated by means of the wheel 40 into the position of use (Fig. 7) so that the dosage chamber 32 of member 30 is aligned with the opening 23 of the pressure reservoir 22 and with the passageway 16 of the mouthpiece 15. The pressurization device 22 is activated and the pressurized medium exits from the pressure reservoir 22 through opening 23 and discharges the powder from the dosage chamber 32 into the passageway 16 from where it is inhaled by the user (air passages 19 in the mouthpiece 15 enable air flow).

This device has a complex structure and requires complex handling: the wheel 40 must be turned to bring the chamber 32 into alignment and the pressurization device 22 must be activated for dispensing.

The present invention differs structurally from *Whaley et al.* in that the supply tube 7 has an integral cylinder wall 8 provided with a through opening 11; the dosage member 30 and the mouthpiece 15 of *Whaley et al.* are separate parts and are not moveable together as a unit. The dosage member 30 requires an external wheel 40 for actuation while in the present invention a simple pivot movement of the supply tube 7 simultaneously moves the cylinder wall 8 with the opening 11.

The mouthpiece 15 is a stationary part of the housing of the device of *Whaley et al.* while the dosage member 30 is rotatably supported in the housing of *Whaley et al.* This configuration does not anticipate or make obvious the configuration of the supply tube 7

with integral cylinder wall 8 as claimed in the present intention. Even though in the cited text portion col. 13, lines 27-35, of *Whaley et al.* it is disclosed that dosage member 30, reservoir 11, passageway 16 or pressure outlet 23 may be mounted for movement, as long as in the load position the chamber 32 opens into the reservoir and in the delivery position the chamber 32 is aligned with the outlet 23 and the passageway 16, this does not teach that the dosage member 30 and the mouthpiece 15 are to be combined to form a single part moveable together. This text portion simply teaches that any part may be made to move but not that parts are to be combined for common movement. Even when it is assumed that the mouthpiece 15 is made moveable as well as the dosage member 30, this cannot teach or suggest to combine the two and make them into a unitary part. This would require a significant restructuring as the mouthpiece is a fixed element of the housing configuration and the member 30 is a complex structure with activation wheel 40.

In the prior art, the medication is located in the opening 32 of the member 30. When member 30 is rotated out of the initial position (Fig. 3) into the position of use (Fig. 5) the substance remains within the opening 32 of the dosage member 30. Pressure created by member 22 and expelled through opening 23 causes the powder to be transferred to the passageway 16 from where it is inhaled by the patient through mouthpiece 15. The medication does not pass from the opening 32 into the opening 23 of the hollow cylinder 22; the opening 23 of the hollow cylinder 22 is provided in order to supply pressurized air and never receives or contains the substance to be inhaled.

According to the present invention in the position of use the dosage unit of the medication has been transferred into the through bore 5 of the stationary cylinder body 4 (in *Whaley et al.* this through bore corresponds to the opening 23 of the cylinder 22) so that the substance is flowing from the opening in the outer cylinder 8 into the through bore 5 of the inner cylinder 4. This is not disclosed in the prior art reference: the medication remains in the chamber 32 of the outer cylinder and does not pass into a through bore of the inner cylinder.

In summarizing the above, the features of the present invention are not anticipated or made obvious by the cited prior art *Whaley et al.*

Rejection under 35 U.S.C. 103

Claims 9, 10, 12 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over

Whaley et al. (US 6,119.688) and *Goldemann et al. (US 6,752,147)*.

In regard to claim 9 it is respectfully submitted that the dosage unit received in the opening 11 of the cylinder wall 8 is transferred in the second position into the through bore 5 by flowing from the opening 11 in the outer cylinder 8 into the through bore 5 of the stationary cylinder 4. This is not shown in *Whaley et al.* where the dosage unit always remains in the chamber 32 of the outer cylinder wall 30 and never enters the outlet 23 of the pressure reservoir. *Goldemann et al.* only teaches an opening at the bottom of the reservoir but nothing of relevance in regard to the subsequent transfer mechanism.

Claim 9 is therefore not obvious in view of the cited art.

Claim 11 stands rejected under 35 U.S.C. 103 (a) as being unpatentable over *Whaley et al. (US 6,119.688)* in view of *Goldemann et al. (US 6,752,147)* and *Mecikalski (US 6,055,980)*.

Claim 8 is believed to be allowable so that the dependent claims are believed to be allowable also.

CONCLUSION

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on November 14, 2008,

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